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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,564	11/14/2003	Orest W. Blaschuk	100086.418	6389
500 7590 12/12/2007 SEED INTELLECTUAL PROPERTY LAW GROUP PLLC 701 FIFTH AVE SUITE 5400 SEATTLE, WA 98104			EXAMINER HADDAD, MAHER M	
			ART UNIT 1644	PAPER NUMBER
			MAIL DATE 12/12/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/714,564	BLASCHUK ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 August 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,4,8,10,11,14,16-25,39-68 and 94-102 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,8,16,17,19-25,39-68 and 94-101 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 10-11, 14, 18 and 102 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

#### DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/27/07 has been entered.
2. Claims 1, 3-4, 8, 10-11, 14, 16-25, 39-68 and 94-102 are pending.
3. Claims 3-4, 8, 16-17, 19-25, 39-68 and 94-101 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.
4. Claims 1, 10-11, 14, 18 and 102 re under examination as the), read on a cell adhesion modulating agent comprises SEQ ID NO:2 or conservative analogue thereof, wherein the peptide present within a linear peptide.
5. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*
6. Claim 102 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a cell adhesion modulating agent consists essentially of the amino acid sequence of SEQ ID NO: 2, does not reasonably provide enablement a cell adhesion modulating agent that inhibits desmosomal cadherin-mediated cell adhesion; and consists essentially of four or five amino acid residues of the sequences Arg-Trp-Ala-Pro-Ile-Pro (SEQ ID NO: 2). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim.

The specification disclosure does not enable one skilled in the art to practice the invention without an undue amount of experimentation.

There is no requirement for the 4 or 5 amino acid residues of sequence Arg-Trp-Ala-Pro-Ile-Pro to be consecutive amino acids from SEQ ID NO:2. Further, the skilled in the art would not know which 4 or five amino acids out of 6 amino acids would inhibit desmosomal cadherin-mediated cell adhesion.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the

nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

7. Claim 102 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of a cell adhesion modulating agent consists essentially of the amino acid sequence of SEQ ID NO: 2.

Applicant is not in possession of a cell adhesion modulating agent that inhibits desmosomal cadherin-mediated cell adhesion; and consists essentially of four or five amino acid residues of the sequences Arg-Trp-Ala-Pro-Ile-Pro (SEQ ID NO: 2) in claim 102.

Besides SEQ ID NO: 2, there is no described or art-recognized correlation or relationship between the structure of the invention, the four or five amino acid residues of sequence Arg-Trp-Ala-Pro-Ile-Pro and its desmosomal cadherin-mediated cell adhesion inhibition, the feature deemed essential to the instant invention. Therefore, one of skill in the art would not envisage, based on the instant disclosure, the claimed four or five amino acid residues of SEQ ID NO:2 which retain the features essential to the instant invention. Since there is no information regarding critical amino acids that are responsible for the claimed function, very little is known about the peptide of SEQ ID NO: 2, and only SEQ ID NO:2 species is disclosed.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

*(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.*

9. Claims 1 and 102 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/10258 (IDS Ref. No. BK).

The '258 publication teaches a compound consisting essentially of a region of the desmosomal cadherin (Dsc2) **RWAPIPCSM**L or **RWAPIPCSM**Q (Dsc3) peptide (see page 4 under Dsc2 and Dsc3 in particular). The two amino acid sequences are Trp-containing compound consisting essentially of a peptide which is 10 amino acids. The extra C-terminal amino acids present in the Dsc2 and Dsc3 would not have adverse effect on the biological activity of the peptides in absence of evidence to the contrary.

The agent of instant claims is included because the agent reads on a compound without a carrier.

While the prior art teachings may be silent as to the “inhibit desmosomal cadherin-mediated cell adhesion” per se; the products the reference are the same as the claimed products. Therefore “inhibit desmosomal cadherin-mediated cell adhesion” is considered inherent properties.

The reference teachings anticipate the claimed invention.

10. Claims 1 and 102 are rejected under 35 U.S.C. 102(b) as being anticipated by WO94/21809.

WO94/21809 publication teaches a compound consisting essentially of Thr Val Leu Arg Arg Ala Lys Arg Arg Trp Ala Pro Ile Pro Cys Ser (see page 47, line 14 in particular). The extra N- and C-terminal amino acids present in the referenced 16 amino acid sequence would not have adverse effect on the biological activity of the peptides in absence of evidence to the contrary.

The agent of instant claims is included because the agent reads on a compound without a carrier.

While the prior art teachings may be silent as to the “inhibits desmosomal cadherin-mediated cell adhesion” per se; the products used in the reference are the same as the claimed. Therefore “inhibits desmosomal cadherin-mediated cell adhesion” is considered inherent properties.

The reference teachings anticipate the claimed invention.

Applicant's arguments, filed 8/27/07, have been fully considered, but have not been found convincing.

Applicant traverses the rejection on the ground that claim 1 has been amended by removing the term “having”. Further, Applicant submits neither WO 97/10258 nor WO 94/21809 teaches a modulating agent as presently claimed, consisting essentially of the amino acid sequence Arg-Trp-Ala-Pro-Ile-Pro (SEQ ID NO: 2), this basis for rejection has been removed.

However, the transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials and those that do not materially affect the basic and novel characteristic(s) of the claimed invention. It is the Examiner's position that the extra amino acid residues present in the reference sequences do not materially affect the basic and novel characteristic of claimed SEQ ID NO: 2 in the absence of evidence to the contrary. Further evidence is illustrated in claim 102, wherein the transitional phrase “consisting essentially of” opens the claim to deletions. Further, evidence come from dependent claims wherein the peptide can be linked to a solid support or the C terminal region of the peptide can be modified with out affecting the peptide's function.

11. Claim 102 is rejected under 35 U.S.C. 102(b) as being anticipated by Chidgey et al (Developmental Dynamics 210:315-327, 1997, of record).

Chidgey et al teach a compound consists of five amino acid residues of SEQ ID NO: 2, WAPIP (see page 316, 2<sup>nd</sup> col., 1st full paragraph in particular).

While the prior art teachings may be silent as to the “modulates desmosomal cadherin-mediated cell adhesion” per se; the product in the reference is the same as the claimed product. Therefore “modulates desmosomal cadherin-mediated cell adhesion” is considered inherent properties.

The reference teachings anticipate the claimed invention.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.*

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/10258 (IDS Ref. No. BK), OR WO94/21809 each in view of in view of U.S. Patent No. 5,455,228.

The teachings of the WO 97/10258 and WO94/21809 have been discussed, supra.

The claimed invention differs from the reference teachings only by the recitation the peptide comprises C-terminal modification which is N-acetylation in claim 11.

The '228 patent teaches the acetylation of the N-terminus is the traditional method for producing a peptide that resists cleavage by aminopeptidase M (col., 2, lines 38-42 in particular).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to N-acetylate the peptide agent taught by the WO '258 or WO '809 as taught by the '228 patent.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because to resist cleavage by aminopeptidase M as taught by the '228 patent.

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

13. Claims 1 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/10258 (IDS Ref. No. BK) OR WO94/21809 each in view of in view of U.S. Patent No. 6,936,587.

The teachings of the WO '258 and WO '809 have been discussed, *supra*.

The claimed invention differs from the reference teachings only by the recitation that the agent is linked to a solid support in claim 14.

The '587 patent teaches that the peptide bound to a solid support, is used to enrich or purify specific antibodies (col., 20, lines 56-67 in particular).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to link the peptide taught by the WO '258 or WO '809 to a solid support as taught by the '587 patent.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so to enrich or purify specific antibodies as taught by the '587 patent.

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

14. Claims 1 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/10258 (IDS Ref. No. BK) OR WO94/21809 each in view of in view of U.S. Patent No. 6,713,450.

The teachings of the WO '258 and WO '809 have been discussed, *supra*.

The claimed invention differs from the reference teachings only by the recitation that the agent in combination with a physiologically acceptable carrier in claim 18.

The '450 patent teaches the synthetic peptides, or conjugates thereof, can be formulated as an immunizing composition using adjuvants, pharmaceutically-acceptable carriers, excipients,

diluents, auxiliary agents or other ingredients routinely provided in immunizing compositions. Such formulations are readily determined by one of ordinary skill in the art and include formulations for immediate release and for sustained release, e.g., microencapsulation (col., 12, lines 53-67 in particular).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate the peptide agent taught by the WO '258 or WO '809 into a composition using pharmaceutically-acceptable carriers as taught by the '450 patent.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because Such formulations are readily determined by one of ordinary skill in the art and include formulations for immediate release and for sustained release as taught by the '450 patent.

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

15. Claims 1 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/10258 (IDS Ref. No. BK) OR WO94/21809 each in view of in view of U.S. Patent No. 6,600,013.

The teachings of the WO '258 and WO '809 have been discussed, supra.

The claimed invention differs from the reference teachings only by the recitation that the amino acids sequence of SEQ ID NO: 2 is C-terminal amidated in claim 10.

The '013 patent teaching presenting the peptide in a conformation which most closely resembles that of the peptide as found in the context of the whole native molecule. For example, the peptides may be altered to have a C-terminal hydrophobic amidated tail (see col., 18, lines 36-40 in particular).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to C-terminal amidated the peptide agent taught by the WO '258 or WO '809 as taught by the '013 patent.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because C-terminal amidation presenting the peptide in a conformation which most closely resembles that of the peptide as found in the context of the whole native molecule as taught by the '013 patent.



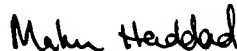
From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 29, 2007

  
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